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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,648	01/20/2004	Patrick S. Pevoto	30368.5	5282
27683	7590	07/02/2004	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/762,648	Applicant(s) PEVOTO, PATRICK S.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01202004</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities:
  - a. In paragraph [0001], at line 2, the current status of the parent application should be updated.
  - b. In paragraph [0011], line 5, "perform" apparently should read --preform--.Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 2-5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-5 recites the limitation "the textured cover" in line 1. There is insufficient antecedent basis for this limitation in the claims. There is a "textured porous means" but no "textured cover" recited in the claims prior to these recitations.

Claim 7 recites the limitation "the form" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no form recited in the claims prior to this recitation.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bucalo in view of Sheldon ('459).

Bucalo ('166) teaches a cell collecting device for testing for the presence of micro-organisms. The cell collecting device **14** includes a shaped absorbent member **16,18** adapted for intra-vaginal insertion; a means **20,20a,20b,26** covering the absorbent member, the means has a plurality of openings **24** (porous) that give the means texture (not smooth), retains the shape of the absorbent member, captures cells residing in vaginal fluids, and passes cells and fluid to the absorbent member; and a means for retrieving the absorbent member **32**. The frame may be a mesh sleeve and may be molded or coated on the absorbent member. Bucalo teaches all of the limitations of the claims except that the cell collecting device includes an intra-vaginal insertion member and means for expelling the absorbent member from the insertion member, i.e. a telescoping tube.

Sheldon teaches a telescoping applicator tube (Fig. 1) for applying a sampling or collection device intra-vaginally. The telescoping applicator tube includes an insertion member **1** and a means for expelling an absorbent member from the insertion member **2**. The applicator tube protects the sampling or collection device from contamination and maintains the integrity of the device during insertion.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a an insertion member and means for expelling an absorbent member from the insertion member similar to that of Sheldon to apply a cell collecting device similar to that of Bucalo in order to protect the sampling device from contamination and to maintain the integrity of the device during insertion.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bucalo ('166) in view of Sheldon ('459), as applied to claim 1 above, and further in view of Buck et al. ('481). Bucalo and Sheldon, as discussed above, teach all of the limitations of the claims except that the cell collecting device is packaged in a single container to form a kit. Buck et al. teach a kit for self-administered intra-vaginal cell collection including cell collection means, a fixative container, shipping means, instructions, and mailing labels. It would have been obvious, in view of Buck et al., to use such a kit for the tampon, telescoping applicator tube, and fixative container of Bucalo as modified by Sheldon in order to make the collection of sampling and collecting materials conveniently available to a consumer for over-the counter purchase for use in the privacy of the home.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 2, 6 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 5-9 of U.S. Patent No. 6,702,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims of the patent require apparatus having the structural limitations of the apparatus claims of the instant application in order to perform the method steps. The structural limitations of claim 1 of instant application are required to perform the method steps of claims 1 and 4 of the patent. The structural limitations of claim 2 of instant application are required to perform the method steps of claim 4 of the patent. The structural limitations of claim 6 of instant application are required to perform the method steps of claims 2, 5 and 7 of the patent. The structural limitations of claim 7 of instant application are required to perform the method steps of claims 8 and 9 of the patent.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Crawford et al. ('435) teach a device for collecting cellular and DNA specimens. Fowler ('494) teach a mucosal cytology cell sampler. Fournier ('165) teaches a cervical specimen self-sampling device. Ward, Jr. et al. ('804) teach a sampling device with a snap-off head.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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June 24, 2004